

REMARKS

I. Claim status

Applicant has amended claims 1, 5, 7, 8, 10-13, 15, 16, 18, 19-22, 26, 30, 45, 51-54, 56, 61 and 62; and added new claims 63-70. Claims 2-4, 6, 9, and 14 were cancelled by earlier amendments. Upon entry of this amendment, claims 1, 5, 7, 8, 10-13, and 15-70 will be pending — claims 1, 5, 7, 8, 10-13, 19-22, and 61-70 are under examination and claims 15-18 and 23-59 are withdrawn. Claims 1 and 7 have been allowed. New claims 63-70 read on the elected invention.

Claims 1, 5, 7, 8, 10-13, 16, 18, 26, 51-54, 56, 61 and 62 have been amended to recite "SEQ ID NO:" instead of "SEQ ID N^o." Claims 8 and 11 were re-written in independent form, and claims 12 and 13 were amended to depend from claim 11. Claims 15, 19, and 21 were amended to avoid reference to cancelled claim 2. Claim 30 was amended to delete an occurrence of "and" and claim 45 was amended to delete an exclamation point. Claims 5, 8, and 10-13 now recite "purified or isolated," and claims 5, and 11-13 recite "nucleic acid from Mycobacterium complex." Claim 8 was amended to recite that the fragment is at least 12 nucleotides. All amendments are made without prejudice or disclaimer.

Support for the claim amendments can be found throughout the application, including, *e.g.*, paragraphs [0005], [0011], [0014], and [0016] of the published application, U.S. Patent Application Publication No. 20060127897, the examples, and the original claims. The amendments do not add new matter and Applicant respectfully requests their entry.

II. Claim objection

Claims 11-13, 19-22, and 60 were objected to for depending from claim 2, which was cancelled. Office Action at 2. Applicant has amended claims 11, 19, and 21, from which the remaining objected-to claims depend, to no longer depend from claim 2, thereby obviating the grounds for objection.

III. Rejections under 35 U.S.C. § 112, second paragraph

Claims 8, 19-22, and 60 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Office, claim 8, which depended from claim 7, allegedly encompassed more species than claim 7. Office Action at 3. Claim 8 no longer depends from claim 7, rendering the rejection moot. The metes and bounds of claims 8, 19-22, and 60 are clear. Accordingly, the rejection should be withdrawn.

IV. Rejections under 35 U.S.C. § 102(b)

The Examiner proffered two separate rejections under 35 U.S.C. § 102(b), over U.S. Patent No. 5,474,796 to Brennan (*Brennan*) and U.S. Patent Application Publication No. 2001/0053519 by Fodor *et al.* (*Fodor*), respectively. The rejections are based on alleged inherent disclosures of nucleotide sequences in these reference's reports of oligonucleotide arrays of all possible 10-mers or 25-mers. Applicant respectfully traverses both rejections.

To anticipate a claim, a single reference must teach every element of the claim. M.P.E.P. § 2131. With regard to inherency, the predecessor to the Federal Circuit stated that a reference cited under § 102 "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need

for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *Application of Arkley* 455 F.2d 586, 587 (C.C.P.A. 1972) (emphasis in original); *see also* M.P.E.P. § 2131.02 (explaining that a generic chemical formula will not anticipate a claimed species unless the classes of substituents are sufficiently limited or well delineated).

Neither of the cited references anticipates Applicant's claims for at least the reason that neither teaches any sequence recited in the claims. In fact, the references provide absolutely no structural constraints on the allegedly inherently disclosed genus of nucleic acid sequences other than their length. These reports are wholly inadequate to anticipate Applicant's claims, which recite specific nucleic acid sequences from *Mycobacterium* complex.

Moreover, even *arguendo* assuming that these references did adequately describe all sequences of 10 or 25 nucleotides, which Applicant does not concede, the amended claims recite that the claimed nucleic acid fragments are purified or isolated. The sequences on the oligonucleotide array of *Fordor* or *Brennan*, in contrast, are not purified or isolated, since the sequences are in a complex mixture of distinct and unrelated sequences—over 10^{15} for a 25-mer array. Accordingly, the sequences cannot reasonably be considered isolated or purified, as recited in the amended claims.

Applicant further addresses the rejections in turn.

A. Brennan

Claims 5 and 8 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by *Brennan*. According to the Office, *Brennan* discloses an array of oligonucleotides

allegedly containing every possible 10-mer, citing to a prophetic Example in *Brennan*.
Office Action at 4.

Brennan teaches only a single specific 10-mer. See *Brennan*'s sequence listing. *Brennan*'s prophetic example does not teach any specific sequences, let alone any sequence recited in the claims, and is therefore entirely inadequate to anticipate Applicant's claims. At most, *Brennan* generically alludes to the genus of all 10-mers, without providing *any* specific sequence information that would describe any subgenus or species relevant to the sequences recited in Applicant's claims. For at least this reason, *Brennan* does not teach all the features of the prior version of Applicant's claims and does not anticipate them.

Nevertheless, in the interest of facilitating prosecution and without acquiescing to the Examiner's reasoning, amended claim 8 recites, *inter alia*, that the fragment is at least 12 nucleotides. Even *arguendo* assuming that *Brennan* inherently reported all possible 10-mers—which Applicant does not concede—*Brennan* fails to teach the nucleic acids recited in amended claim 8, which, *inter alia*, are at least 12 nucleotides long.

With regard to claim 5, Applicant notes that SEQ ID NOs: 17 and 18 are each 20 nucleotides long. A nucleic acid fragment obtained by amplification with these primers would include the sequence of these two primers and therefore be greater than 10 nucleotides long. Accordingly, for at least this reason, *Brennan* does not teach the nucleic acid recited in claim 5.

To further illustrate that claim 5 is not anticipated by *Brennan*, Applicant notes that SEQ ID NOs: 17 and 18 flank a region that is polymorphic between certain tubercle

bacilli. See, e.g., paragraphs [0042] and [0077] of the published application, discussing the TbD1 deletion region; see also Figure 5, which provides a schematic diagram of this region, including the location of primers provided by the invention, in different mycobacteria. Figure 1 in the application shows the size of amplicons of the TbD1 region from a variety of mycobacteria, which have approximate sizes of 2600 or 500 bp. *Brennan* clearly does not teach (let alone fairly suggest) such sequences and does not anticipate claim 5.

Applicant respectfully requests that this rejection be withdrawn.

B. Fodor

Claims 5, 8, 10, 61 and 62 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by *Fodor*. According to the Office, *Fodor* teaches solid supports comprising all oligonucleotides 2, 10, or 25 nucleotides in length, “and therefore inherently comprised SEQ ID NOs: 13-18.” Office Action at 4. Applicant respectfully traverses.

Fodor merely describes the production of an array of 10-mers and does not teach the sequence of any nucleic acid on the array, let alone any sequence recited in the claims. With regard to arrays of sequences longer than 10 nucleotides, *Fodor* does no more than merely prophetically allude to such arrays, and again fails to describe any subgenus or species of sequence relevant to Applicant’s claims. Accordingly, *Fodor* does not teach (or even fairly suggest) a fragment of SEQ ID NO:1 or 4, at least 12 nucleotides in length (as recited in claims 8, 10, and 11) or the 20-mers of SEQ ID NOs: 13-18—let alone pairs of these 20-mers or fragments amplified from *Mycobacterium* complex with them, as recited in, for example, claims 5, 11, or 62. See also arguments regarding claim 5 under the previous subheading.

In short, *Fodor* does not teach all of the features of claims 5, 8, 10, 61, and 62 and does not anticipate them. Accordingly, the rejection should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims. The Examiner is encouraged to contact the undersigned with any questions to facilitate prosecution.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

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Respectfully submitted,

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